
Yale University Human Research Protection Program

920 PR.1 Research Affiliate Requests

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Overview

This procedure outlines the process for review and approval or denial of requests by non-Yale institutions to obtain Research Affiliate status with Yale University in order to participate in federally funded research conducted by a Yale principal investigator. Research Affiliate status is required when an institution external to Yale requests to designate one or more of the Yale IRBs as its IRB(s) of record on their Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP).

Initiation of Requests

Requests for an institution to become a Yale Research Affiliate may be generated by the Yale Principal Investigator or a representative from the external institution. Requests may be initiated in anticipation of conducting a single protocol, or with the expectation that inter-institutional collaboration is required for multiple protocols. Inquiries regarding Research Affiliate status should be directed to the Education and Community Outreach Manager (Manager). With rare exception, research affiliation is limited to studies in which a Yale University full time faculty member serves as principal investigator.

Application Process

The Manager will work with the potential Affiliate in completing the application process. The following documents must be provided by the potential Affiliate:

1. the Yale Request for Permission to Designate Yale University's Institutional Review Board(s) (IRB) As IRB of Record For Research Involving Human Subjects;
2. a draft FWA application;
3. documentation of completion by the Signatory Official and Human Protections Administrator of OHRP's Human Subjects Assurance training modules 1, 2, and 3. Documentation of completion of Yale University's HIPAA for Researchers training for HIPAA covered entities or those institutions working with HIPAA covered entities;
4. institutional human research policies, including, at a minimum all elements outlined on the Research Affiliate web site located on Yale's HRPP site;
5. affiliate institutional policies regarding the review and approval/disapproval of research project proposals performed at or with the affiliate institution.

Upon receipt of the above materials, the Manager will evaluate the request using the Staff Evaluation Form.

Staff Evaluation

The staff evaluation must incorporate the following information:

1. a description of the Yale research project generating the request for research affiliation. The description should include specific protocol information as well as any known plans for continued research with the Affiliate.
2. the applicant institution's background, including type of organization, services offered, length of time in business, licensing and accreditation information (if applicable), number of employees, tax status, and any other relevant information;
3. information regarding the Signatory Official and Human Protections Administrator, including their role in the institution, educational background, relationship, if any, to Yale University, human subjects protection and HIPAA training (if applicable), and any other relevant information;
4. a description of the institution's research policies, including information regarding any special policies that have been developed to meet either the needs of their research participant population or institutional structure;
5. information on whether or not Yale IRBs will serve as HIPAA Privacy Board for research conducted in conjunction with the partnership
6. any other information deemed relevant.

Staff Recommendation

Based on the staff evaluation, the Manager will develop a recommendation regarding the request for research affiliation. The recommendation may be to approve or not to approve research affiliation. If the recommendation is to approve, the Manager will develop a draft IAA, designating which Yale University IRBs are included in the agreement. Designation of IRBs is determined by which IRB is best qualified to review the proposed research project and by expectations regarding the nature of potential future projects.

Review of Staff Recommendation

The staff evaluation, with recommendation and copies of the request, FWA application, documentation of training, research policies and a draft IAA are forwarded to the IRB Director for review. Requests for revisions to the Affiliate's documents or the staff evaluation and recommendation may be made as part of this review.

All recommendations by the Manager and the Director (those recommending approval of Research Affiliate status and those recommending not to approve Research Affiliate status) are submitted to the Yale Institutional Signatory Official for review. If deemed necessary by the IRB (e.g., if there is a potential conflict of interest), materials may be submitted to the Office of General Counsel as well. A pdf file containing the recommendation, application and draft IAA (if applicable) is sent by the Manager, with a copy to the Institutional Signatory Official's senior administrative assistant. If the recommendation is to approve the Institution as a Research Affiliate, a Word version of the policies is sent with the pdf file.

In those circumstances where the Office of the General Counsel reviews the materials, counsel may request added information, request modifications to the IAA, approve the Affiliate request and IAA as proposed, or not approve the partnership request. When the Office of the General Counsel has made a final determination regarding approval, counsel notifies the Institutional Signatory Official, IRB Director and the Manager.

Notification to Affiliate

If the affiliation is approved, and the research Affiliate is local, the Manager schedules a meeting with the Affiliate, the researcher whose request initiated the affiliation, the IRB Director and the Manager. At this meeting the terms of the IAA are reviewed and expectations of each party are discussed and clarified. Information regarding IRB support and oversight services is provided. This meeting provides an opportunity for the Research Affiliate to pose any questions concerning their responsibilities as an Affiliate and their relationship to Yale University. If the research Affiliate is not local, two copies of the IAA are mailed to the Affiliate Signatory Official to be signed, with one copy to be returned to the Manager. A

cover letter, encouraging the Affiliate Signatory Official to contact the Manager with any concerns or questions, is sent with the IAA.

If the affiliation is not approved, the Manager notifies both the Institution requesting affiliation and the researcher who initiated the request of the reason for denial and information on alternatives to Yale University research affiliation.

IAA Term

The initial IAA is for a three year term. The term may be three years from the date the IAA was executed (for Affiliates with existing FWAs), or three years to coincide with the period of the FWA (for Affiliates filing an FWA application after execution of the IAA). Renewal IAA terms may differ. (See Procedure 920.4-Renewal of IAAs.)

IAA Execution and FWA Application

The IAA is signed by the Yale Institutional Signatory Official prior to the Affiliate meeting. The Manager is responsible for providing the Institutional Signatory Official's senior administrative assistant with final language for the IAA. The senior administrative assistant generates two copies of the IAA for the Institutional Signatory Official's signature, and sends the signed copies to the Manager. The Affiliate's Signatory Official signs the copies at the Affiliate meeting, if local, or via mail if no meeting will be held. One original copy is kept by the Affiliate Signatory Official; the second copy is kept by the Manager. A pdf of the signed copy is sent to the Yale Institutional Signatory Official.

When the IAA has been signed by both parties, the Affiliate is authorized to file its FWA application. If the Affiliate already has an FWA, the FWA may be updated to include the designated Yale University IRBs covered in the IAA when the IAA has been signed by both parties.

Each Institution receives notice from OHRP when one or more of the Yale IRBs have been designated in the external institution's FWA and the filing is complete.

Documentation

The Manager retains a hard copy file of the Affiliate request, including all materials developed pursuant to the request, and all e-mails generated by OHRP regarding the Affiliate FWA. An electronic file is also maintained for each Affiliate, containing all materials developed pursuant to the request. These copies can be made available to others upon request.

Reference:

OHRP Federalwide Assurance (FWA) For The Protection of Human Subjects, Terms of the Federalwide Assurance (FWA) for Institutions within the United States

Yale University Research Affiliate Web Site: <http://yale.edu/hrpp/ra.html>